

REMARKS

The Examiner states that restriction of the pending claims into one of the following three groups is required under 35 U.S.C. § 121:

- Group I: Claims 1-2, drawn to a genetically altered animal defective in Caspase-9 expression;
- Group II: Claims 3-5, drawn to a method of making a genetically altered animal defective in Caspase-9 expression; and
- Group III: Claims 6-7, drawn to a method of treating or preventing cell death associated with viral infection in an animal.

The Examiner asserts that the inventions are distinct from one another, such that applicants must elect one group of inventions for examination.

Specifically, the Examiner states that inventions I and II are patentably distinct because an animal of Group I could be made by methods that are materially different from an embryonic stem cell method of Group II. The Examiner asserts that inventions I and III are unrelated because one cannot use an animal of Group I, which lacks Caspase-9 expression, to perform a method of Group III. The Examiner also states that inventions II and III are unrelated because an animal produced by the method of Group II lacks Caspase-9 expression and, therefore, cannot be used in a treatment or prevention method of Group III.

Applicants traverse the restriction between the inventions of Groups I and II. The Manual of Patent Examining Procedure (MPEP) states that there are two criteria for a proper

requirement of restriction between patentably distinct inventions. The inventions must be independent or distinct as claimed, and there must be a serious burden on the Examiner if restriction is not required. The MPEP further states that “[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” MPEP § 803. Applicants respectfully request that the Examiner reconsider his restriction requirement in view of these criteria.

The methods of Group II are used to make the animals of Group I. It follows that a search for the inventions of Group I would necessarily be co-extensive with a search for the inventions of Group II. The grouping of Group II with Group I, therefore, poses no additional search burden on the Examiner, much less a serious search burden. Accordingly, Groups I and II should be examined together.

Applicants, therefore, respectfully request that the Examiner consider Groups I and II together. If the Examiner disagrees with this proposal, pursuant to 37 C.F.R. § 1.143, applicants provisionally elect with traverse the claims of Group I for initial substantive examination.

This election is made expressly without waiver of applicants’ rights to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or in other applications claiming priority herefrom.

The Examiner further states that restriction of the claims of Group III into the following five species is required under 35 U.S.C. § 121:

- Species A: Monoclonal antibody;
- Species B: Polyclonal antibody;
- Species C: Oligonucleotide that specifically hybridizes to Caspase-9 DNA;
- Species D: Oligonucleotide that specifically hybridizes to Caspase-9 mRNA; and
- Species E: Ribozyme.

The Examiner asserts that Species A-E are patentably distinct species of molecules that inhibit either the expression or the activity of Caspase-9. The Examiner requires that applicants elect a single disclosed species for prosecution on the merits. Applicants believe that because they are not presently pursuing the claims of Group III, no species election is necessary at this time. Applicants, therefore, defer their response to this species election requirement. Applicants have contacted the USPTO in an attempt to determine whether a species election in non-elected Group III is required at this time but have not received a response.

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Applicants, thus, have made a good faith attempt to fully respond to the outstanding Office Action. If the Patent Office determines that an election of species in non-elected Group III is in fact required at this time, applicants stand ready to provide such election.

Respectfully submitted,



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James F. Haley, Jr. (Reg. No. 27,794)  
Jane T. Gunnison (Reg. No. 38,479)  
Jennifer T. Weissman (Reg. No. 40,868)  
Attorneys for Applicants  
FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
Customer No. 1473  
1251 Avenue of the Americas  
New York, New York 10020-1104  
Tel.: (212) 596-9000  
Fax: (212) 596-9090